Alliance for Fair Trade with India

October 31, 2019

Edward Gresser
Chair, Trade Policy Staff Committee
Office of the U.S. Trade Representative
Executive Office of the President
600 17th Street, NW
Washington, D.C. 20508

RE: Comments Regarding Foreign Trade Barriers to U.S. Exports for 2019 Reporting, Docket Number USTR-2019-0012

Dear Mr. Gresser:

The Alliance for Fair Trade with India ("AFTI") is comprised of a diverse group of organizations that support a robust U.S.-India economic relationship but believe that the relationship has long underperformed its potential, in part due to longstanding trade and investment barriers. In light of its mandate, AFTI provides comments to the Office of the United States Trade Representative ("USTR") for its 2020 National Trade Estimate Report on Foreign Trade Barriers ("NTE Report"), specifically regarding India.

AFTI members appreciate USTR's push for a more robust and reciprocal U.S.-India economic relationship, especially through bilateral talks that have taken place since June 2018. Despite USTR's diligent work over several months, India has yet to address the serious and costly concerns raised by USTR. AFTI firmly hopes that these trade talks succeed in the very near term, and urges India to take the steps necessary for them to succeed by agreeing to tangible progress. That progress can create momentum for a new economic relationship that achieves the goal set by President Donald Trump and Prime Minister Narendra Modi in June 2017 "of expediting regulatory processes; ensuring that technology and innovation are appropriately fostered, valued, and protected; and increasing market access in areas such as agriculture, information technology, and manufactured goods and services."[1]

In these comments, we describe the wide variety of onerous, costly, and cross-cutting market access barriers that many of America's most globally competitive industries currently face in India, including (1) weak protection of intellectual property rights, (2) high tariffs and tariffs inconsistent with India's World Trade Organization ("WTO") commitments, (3) price controls, (4) forced localization, (5) discriminatory testing requirements, (6) discriminatory labeling standards, and (7) an effective ban on dairy imports. Further, India undermines the market access of American producers in other countries by working within international organizations to weaken global intellectual property enforcement. As noted by the U.S. Commercial Service, "India has strongly supported and sometimes led the charge in calling for open technology transfer, liberal

[1] The White House, United States and India: Prosperity Through Partnership (June 2017), https://www.whitehouse.gov/briefings-statements/united-states-india-prosperity-partnership/.

use of compulsory licensing cross sectors, price controls and protection of traditional knowledge."[2]

I. Weak Protection of Intellectual Property Rights

A. Copyright

1. Section 31D of the Copyright Act of 1957

Section 31D of the Copyright Act of 1957 (as amended in 2012) concerns the broadcasting or performance of a literary or musical and sound recording. It was originally intended to have a limited scope; statutory licenses would be required for non-interactive radio and television broadcasting, but not for internet music streaming services. In September 2016, however, the Modi Administration issued a memorandum on section 31D expanding the scope of statutory licenses to apply to all kinds of broadcasting, including internet broadcasting. By including internet music streaming services under section 31D, the memorandum is inconsistent with clearly defined international copyright law, including the World Intellectual Property Organization ("WIPO") Berne Convention and WIPO Internet Treaties. India is departing from worldwide commercial practice in which digital music services are licensed individually on free market terms.

2. Internet/Camcording Piracy and Illegal Downloading

India's failure to protect copyrights allows for widespread theft of American products across multiple industries. The problem is growing and serves as a significant barrier to U.S. exports of goods and services, as well as U.S. foreign direct investment. India is ranked 36th out of the fifty countries listed in the International IP Index created by the Global Innovation Policy Center of the U.S. Chamber of Commerce, and scored a 2.22 out of a possible seven for copyright protections in 2019.[3] The problem is daunting. Piracy of movies, music and illegal downloads in India is estimated to cost the music and entertainment industry approximately $4 billion per year, the bulk of which affects local content. However, AFTI does commend the High Court of Delhi, the High Court of Bombay, Maharashtra Cyber Digital Crime Unit, the Telangana Intellectual Property Crime Unit, and the National Internet Exchange of India for continuing to provide content creators meaningful injunctive relief against websites offering pirated and infringing content, and the Department of Telecommunications for helping to carry out the orders. AFTI encourages this work to continue.

Notably, in February 2019, India's Cabinet approved anti-camcording provisions in the Cinematographic Amendment Bill 2019 that would criminalize any nonconsensual recording and transmission of audiovisual works using any audiovisual devices, given that "[f]ilm piracy, particularly release of pirated version of films on the internet, causes huge losses to the film

[2] International Trade Administration (ITA), U.S. Department of Commerce. "India - Protecting Intellectual Property" https://www.export.gov/apex/article2?id=India-Protecting-Intellectual-Property

[3] U.S. Chamber of Commerce Global Innovation Policy Center, "Inspiring Tomorrow: U.S. Chamber International IP Index" (2019), available at https://www.uschamber.com/ipindex .

industry and government exchequer."[4] AFTI welcomes these proposed amendments, which have been referred to parliament. If adopted, they would better protect intellectual property for producers and distributors of entertainment content in both the United States and India.

B. Patents

1. Compulsory Licensing

The threat of a compulsory license ("CL") is often used as a negotiating tactic and industrial policy tool in India to compel local manufacturing, particularly in the pharmaceutical and agriculture biotechnology industries. USTR explained in its 2019 NTE Report that the United States "continues to monitor India's application of its compulsory licensing law."[5] AFTI believes that India's compulsory licensing policies and practices continue to be a significant barrier to trade. The grounds for issuing a CL in India are broad, vague, and inconsistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS Agreement"). India also has sought to use CLs to promote local production at the expense of U.S. manufacturers and workers. Such practice is discriminatory and inconsistent with India's international obligations.

For example, India's Ministry of Health continues to entertain potential recommendations to impose CLs on certain anti-cancer medicines under Section 92 of India's Patents Act, a special provision that provides the Government of India with discretion in issuing CLs.[6] Moreover, Indian pharmaceutical companies continue to make requests for voluntary licenses under Section 84(6)(iv) of the Patents Act; rather than using this CL measure as a last resort, these companies are inappropriately utilizing a CL strategy as a commercial tool.[7] Even though the pace at which the Indian government has granted CLs may have slowed in recent years, India's underlying policy framework in support of CLs remains a major concern for innovative U.S. companies.

2. Section 3(d) of the Patents Act, 1970

Under Section 3(d) of the Patents Act, 1970, India has created an impermissible hurdle for patenting medicines that is out of step with global rules and norms. Article 27 of the TRIPS Agreement requires that an invention be entitled to patent protection as long as it is new, involves an inventive step, and is capable of industrial application.[8] In contrast to this baseline three-part patentability test, Section 3(d) of the Patents Act adds an impermissible fourth substantive criterion of "enhanced efficacy."[9] This additional patentability hurdle, which was reinforced by the Pharmaceutical Patent Examination Guidelines issued in October 2014,[10] not

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[4] *Public Comments Sought on Cinematograph Act (Amendment) Bill*, Jan. 3, 2019, https://mib.gov.in/sites/default/files/Public%20Notice%20-%20Amendment%20of%20Cinematograph%20Act%20Bill.pdf.

[5] 2019 NTE Report at 248.

[6] India Patents Act § 92(1).

[7] Id. § 84(6)(iv).

[8] TRIPS Agreement, Article 27.1.

[9] India Patents Act § 3(d).

[10] Office of the Controller General of Patents, Designs and Trademarks, Guidelines for Examination of Patent Applications in the Field of Pharmaceuticals (Oct. 2014),

only undermines incentives for critical medical innovations, but also is inconsistent with the patentability framework under the TRIPS Agreement. Restrictions that narrow patentability prevent innovators from building on prior knowledge to develop valuable new and improved treatments that can enhance health outcomes.[11] Such improvements can also lead to reduced costs by making it easier for patients to take medicines and improve patient adherence to prescribed therapies. Moreover, the additional hurdle required by Section 3(d) appears to target pharmaceuticals specifically, contrary to India's international obligations not to discriminate against a field of technology.[12]

India has refused to address the challenges posed by Section 3(d), despite their inclusion year after year in USTR's reports and repeated attempts by the U.S. government to engage creatively on these issues. Section 3(d) not only is inconsistent with India's core patentability and non-discrimination obligations, but also is an ineffective and inherently flawed policy. The Modi Administration is continuing to ignore repeated calls to rectify this onerous and WTO-inconsistent standard for patentability to the detriment of both foreign and Indian IP holders.

C. Confidential Test Data and Trade Secret Protection

1. Continued Lack of Confidential Test Data Protection

In its 2018 NTE Report, USTR noted that India "lacks an effective system for protecting against unfair commercial use, as well as unauthorized release of undisclosed test or other data generated to obtain marketing approval for pharmaceutical and agricultural products."[13] Despite repeated urgings by USTR, India continues to provide inadequate protection for IP holders, in violation of its international obligations and global IP standards.

As an example, the Indian government requires U.S. companies to submit extensive and valuable information for evaluation before bringing a product to market.[14] Data protection is critical at this stage. In the biopharmaceuticals context, U.S. companies spend an average of 10 to 15 years investing in research and development ("R&D") for a new product, at a tremendous cost. Some have estimated that "[t]he development of test data typically represents more than sixty percent of the R&D costs of new drugs."[15] In the plant science industry, the cost and time required to develop core products is high: $256 million and approximately 10 years for a crop protection product and $136 million and over 13 years for plant biotechnology products.[16]

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http://www.ipindia.nic.in/writereaddata/Portal/IPOGuidelinesManuals/1_37_1_3-guidelines-for-examination-of-patent-applications-pharmaceutical.pdf.

[11] As USTR noted in its most recent report on foreign trade barriers, Section 3(d) "may have the effect of limiting the patentability of an array of potentially beneficial innovations." 2019 NTE Report at 248.

[12] TRIPS Agreement, Article 27.1.

[13] 2019 NTE Report at 248.

[14] Central Drugs Standard Control Organization, Guidance For Industry,

http://www.ayushmuhs.in/public/Guidelines/CDSCO.pdf.

[15] Carlos M. Correa, Protecting Test Data for Pharmaceutical and Agrochemical Products Under Free Trade Agreements, UNCTAD-ICTSD (2004), http://www.iprsonline.org/unctadictsd/bellagio/docs/Correa_Bellagio4.pdf.

[16] Croplife International, Five Things You Need to Know About Agricultural Innovation and Intellectual Property (2013), https://croplife.org/news/five-things-you-need-to-know-about-agricultural- innovation-intellectual-property/https://croplife.org/news/five-things-you-need-to-know-about-agricultural-%20innovation-intellectual-property/

India does not provide meaningful protection for this regulatory data, and the Modi Administration has not made any notable improvements to the regulatory framework for data protection. The absence of regulatory data protection creates an unfair commercial advantage for generic companies in India. India must implement effective and meaningful periods of regulatory data protection.

2. Continued Lack of Trade Secret Protection

Currently, India does not have a unified law to protect information that qualifies as a "trade secret" under international law, as defined by Article 39.2 of the TRIPS Agreement.

Here, U.S. companies primarily must rely on Indian contract law to protect their trade secrets. India's Contract Act of 1872 does not include provisions for trade secrets, but does void contractual agreements that are "in restraint of trade." Thus, it is both difficult and laborious for companies to protect trade secrets through these means; contracts must be drafted with great precision, yet overly-onerous contracts can become open legal dispute. Criminal remedies are generally not available; instead, Indian courts primarily rely upon contract and tort law principles.[17] This severely impacts U.S. companies attempting to access Indian markets, as these companies are forced to rely on Indian courts to ultimately decide issues of trade secrets protection.

Additionally, before bringing a product to market, the India government requires U.S. companies, including those in the pharmaceutical and bio-agricultural industries, to submit valuable trade secret information that may be protected by various levels of patents in the United States. This exposes U.S. companies to the potential for theft of trade secrets, undermining the extensive research and development costs incurred to develop the protected innovation.

The 2019 NTE Report explains that there is a bilateral effort to eliminate gaps in India's trade secrets regime, such as through the adoption of standalone trade secrets legislation.[18] AFTI hopes that continued bilateral engagement can lead to a fruitful resolution.

II. Tariffs

Compared to other Asian countries in similar stages of development, import duties in India are very high. Tariffs on non-agricultural goods in India are about four times more than the average United States tariff rate. India maintains high tariffs on a range of manufactured products to protect its domestic industries, including automobiles, motorcycles, textiles, distilled spirits, pharmaceuticals, and rubber.

Imported spirits into India face a tariff of 150 percent, which severely restricts access for U.S. spirits exporters to the world's largest market for whiskey, valued at $25 billion in 2017. Innovative pharmaceutical companies operating in India face high effective import duties for active pharmaceutical ingredients and finished products, averaging about 10 percent, while

[17] Tariq Ahmad, Protection of Trade Secrets – India, Library of Congress (April 2013), https://www.loc.gov/law/help/tradesecrets/india.php.

[18] 2019 NTE Report at 230.

excessive duties on the reagents and equipment imported for use in research, development, and manufacture of biotech products make biotech operations difficult to sustain. The Integrated Goods and Service Tax imposed on imports can result in the effective import duty exceeding 20 percent, while India does not provide a commercially meaning de minimis threshold for commercial shipments.

Nor has India refrained from adjusting its tariff levels to protect its domestic commercial interests and discriminate against imports. India maintains large gaps between their bound tariff rate and the applied rate. In each Union Budget since Prime Minister Modi entered office, India has increased tariffs across multiple sectors, including processed foods, electronics, auto components, footwear, and furniture. Local groups have used these and other national policies to promote protectionism by seeking relief from foreign competition through tariff hikes. The budgets have been consistent with the protectionist elements of Prime Minister Modi's "Make in India" campaign, which promotes manufacturing in India but often bolsters efforts to pressure companies to localize manufacturing or to promote local manufacturers at the expense of foreign companies and imported products. Another example is India's increased tariffs on information technology products, including on many products that should enjoy duty-free treatment in accordance with India's commitments as a signatory to the WTO Information Technology Agreement.

III. Price Controls

A. Medical Device Price Controls and Procurement Policies

Since 1996, India has maintained a National List of Essential Medicines ("NLEM"), a list designed to capture medicines (including pharmaceuticals and medical devices) deemed to improve the quality of health care. The National Pharmaceutical Pricing Authority ("NPPA") may regulate the prices of those items listed on the NLEM. In early 2017, NPPA issued an order that capped the price of coronary stents resulting in a nationwide cut of stent prices by 75-85 percent.[19] The NPPA also issued a similar order in August 2017 on knee implant systems.[20]

By establishing a uniform ceiling price regardless of their level of technology or the clinical data supporting their safety and performance, this decision harmed U.S. companies that produce the most innovative stent and knee implant technologies. By setting a single price category across newer and older technologies, the order rewards the less advanced products not backed by the investment in R&D and clinical research needed for the innovative products of U.S. companies.

In addition, in March 2018, the Department of Pharmaceuticals issued an order mandating local content requirements ranging from 25-50 percent for medical devices sold in the public market.[21] These pricing and procurement decisions do not adhere to the need for transparency,

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[19] Order, National Pharmaceuticals Pricing Authority (Feb. 13, 2017), http://nppaindia.nic.in/ceiling/press13Feb2017/so412e-13-02-17.pdf.

[20] Teena Thacker, After Stents, NPAA Puts a Price Cap on Knee Implants, LiveMint (Aug. 17, 2017), https://www.livemint.com/Politics/AVfhAyvbr6NZAk19ugQT9H/Govt-cuts-knee-implant-prices-to-much-lower-than-market-rate.htmlhttps://www.livemint.com/Politics/AVfhAyvbr6NZAk19ugQT9H/Govt-cuts-knee-implant-prices-to-much-lower-%20than-market-rate.html.

[21] Guidelines For Implementation of "Public Procurement (Preference to Make In India) Order – 2017" – reg. (Mar. 15, 2018),

predictability, and trust in the decision-making process, hindering the industry's ability to further invest in India and deliver innovative technologies to Indian patients. The local content requirements are due to increase as the program is phased in this year and next.

B. Pharmaceutical Industry

Despite decades of government price controls in India, essential medicines still are not easily accessible. Yet, India has thousands of manufacturers of pharmaceuticals that operate in a very competitive environment and, as a result, some of the lowest prices of medicines in the world.[22] Focusing on the key barriers to access in India – such as insufficient health care funding, infrastructure, and quality – rather than price controls, would significantly improve access to medicines for patients. A 2015 study by IMS Health found that price controls are neither an effective nor a sustainable strategy for improving access to medicines. The study further found that the primary beneficiaries of price controls have been high-income patients, rather than the intended low-income population.[23]

Drug Price Control Order ("DPCO") 2013 sought to establish price stability by setting ceiling prices for medicines listed on Schedule I every five years. Despite doing so in 2013, the NPPA announced in June 2016, per Paragraph 18 of the DPCO 2013, that it would set new ceiling prices for all medicines, including those for which a ceiling price already had been set only three years prior. These pricing decisions, as well as the broad authority granted to the NPPA under this provision, do not respect the need for transparency, predictability, and trust in the decision-making process, and ultimately negatively impact patient access to medicines. Furthermore, frequent repricing imposes an unnecessary administrative burden, due to the need to recall and re-label medicines to reflect the new prices, and in turn can result in product shortages.

AFTI welcomes the actions taken by the Department of Pharmaceuticals ("DOP") in January 2019 to revise Paragraph 32 of the DPCO 2013. These revisions exempt from the pricing formula, for a period of five years, all new medicines, not just those developed through indigenous research and development. This action creates an equitable playing field for both local Indian companies and American and other foreign pharmaceutical companies, in line with India's national treatment obligations. Additionally, DOP created an exemption for orphan drugs from price controls, although the Government of India has yet to define "orphan drug" anywhere in statute, a step that we encourage DOP to take forthwith.

C. Agricultural Biotechnology Industry

Price controls for the agricultural biotechnology industry in India create barriers for U.S. companies and depress further investment in the Indian market. For example, cotton seeds are covered in the Essential Commodities Act, 1955, which provides for central government control of the production, supply, and distribution of certain key commodities if necessary. However, the Government of India has delegated its pricing authority to individual states, which are setting maximum sales prices.

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http://pharmaceuticals.gov.in/sites/default/files/Guidelines%20for%20implementation%20of%20Public%20procurement.pdf.

[22] Analysis based on IMS MIDAS Data.

[23] IMS Health, Assessing the Impact of Price Control Measures on Access to Medicines in India, June 2015.

AFTI and its members were concerned with the draft Licensing Guidelines and Formats for Genetically Modified Technology Agreements ("Licensing Guidelines") issued in May 2016. In response to significant opposition from industry, the Licensing Guidelines, originally in final form, were withdrawn and reissued as a draft for comments from the public.[24] Nonetheless, the draft proposed Licensing Guidelines would have forced Monsanto – the company that manufactured the successful genetically modified ("GM") Bt Cotton seed that so dramatically improved crop yields and the livelihood of Indian farmers[25] – and other biotech companies to share their technology with local seed companies. As such, they have only contributed to the uncertain business and regulatory environment in India. As a result, in August 2016, Monsanto made the decision to withdraw its application seeking approval for its next generation of GM cotton seeds in India.[26]

However, we were very pleased to see Monsanto's victory in India's Supreme Court, overturning a "Delhi High Court order saying that the American giant can't claim patent on its GM cotton seeds."[27] This decision sets a thoughtful precedent that, if followed, could increase yields for Indian farmers and boost American agricultural biotechnology exports to India.

IV. Forced Localization

In addition to the local content requirements for medical devices described above, India has implemented a series of deeply concerning forced localization measures that limit the access of U.S. industries to the Indian market, including tariffs on IP-intensive products. India has also recently proposed data localization measures that include the draft national e-commerce policy framework,[28] a draft cloud computing policy requiring local storage of data,[29] and the draft Personal Data Protection Bill.[30] The Personal Data Protection Bill would require companies to store a copy of all "personal data" in India, while subjecting "sensitive" personal data to stronger requirements and mandating that "critical" personal data only be processed within India. In April 2018, the Reserve Bank of India issued a now-implemented directive requiring that data related to

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[24] Department of Agriculture, Cooperation & Farmers Welfare, Government of India, http://agricoop.nic.in/.

[25] Association of Biotechnology Led Enterprises, Keeping farmer interest in mind Association of Biotech Led Enterprises – Agriculture Focused Group (ABLE- AG) opposes Government`s Cotton Seed Price Control Order (Dec. 21, 2015), http://ableag.org/wp-content/uploads/2016/01/Keeping-farmer-interest-in-mind-Association-of- Biotech-Led-Enterprises-Agriculture-Focused-Group-ABLE-AG-opposes-Governments-Cotton-Seed-Price-Control-Order.docx.

[26] Mayank Bhardwaj, "Exclusive: Monsanto Pulls New GM Cotton Seed From India in Protest," Reuters (Aug. 25, 2016), http://www.reuters.com/article/us-india-monsanto-idUSKCN10Z1OX.

[27] "SC rules in favour of Monsanto's patent of GM Cotton seeds," Indo-Asian News Service. (Jan. 8, 2019). https://www.business-standard.com/article/news-ians/sc-rules-in-favour-of-monsanto-s-patent-of-gm-cotton-seeds-119010801370_1.html,

[28] Sankalp Phartiyal and Aditya Kalra, India Looking to Compel E-Commerce, Social Media Firms to Store Data Locally, Reuters (July 30, 2018), https://www.reuters.com/article/us-india-ecommerce/india-looking-to- compel-e-commerce-social-media-firms-to-store-data-locally-idUSKBN1KK0IZ.

[29] Adiyta Kalra, "Exclusive: India Panel Wants Localization of Cloud Storage Data in Possible Blow to Big Tech Firms," Reuters (Aug. 4, 2018), https://in.reuters.com/article/us-india-data-localisation-exclusive/exclusive- india-panel-wants-localization-of-cloud-storage-data-in-possible-blow-to-big-tech-firms-idINKBN1KP08J.

[30] Government of India, Ministry of Electronics & Information Technology, Data Protection Framework, http://meity.gov.in/data-protection-framework.

payment transactions be stored only in India for "unfettered supervisory access."[31]

India's recent actions build on concepts included in India's Machine-to-Machine Roadmap for the development and deployment of Internet of Things ("IOT") technologies, launched in 2015, but has not been implemented. The Roadmap introduced the possibility of India's first local data storage requirement by requiring that all IOT gateways and application servers that supply customers in India be located in India.[32] The Roadmap also sought to localize production of IOT goods by setting a goal that local manufacturers produce 80 percent of IOT products procured by the Indian public sector by 2020.

Local content requirements affect several other IP-intensive, high-tech sectors such as solar energy and telecommunications. In 2016, the United States won its challenge of India's local content requirements for solar energy projects when the WTO affirmed that India had in fact violated the national treatment obligations in Article III:4 of the General Agreement on Tariffs and Trade 1994 and Article 2.1 of the Agreement on Trade-Related Investment Measures.[33] Pursuing forced localization for commercial measures rather than national security purposes is in violation of India's international obligations.

V. Discriminatory and Duplicative Testing Requirements

U.S. companies in India across an array of sectors face a range of testing and certification requirements that are duplicative to tests American exporters undertake in internationally accredited labs. These include the Compulsory Registration Order for safety testing, in effect since 2013, as well as a range of sector-specific testing and certification requirements, such as local telecom security testing, testing and certification procedures for ICT equipment sold to telecommunications operators, and duplicative local testing for sectors such as toys. Many of these testing requirements deviate significantly from internationally accepted safety and certification norms and protocols and would be practically impossible for American manufacturers to comply with.

In some cases, there is not even sufficient Indian testing capacity to implement these requirements, at best requiring time-intensive, duplicative testing processes and at worse risking effective blocks from the market. For years, India has delayed a testing mandate for ICT equipment. On October 1, 2019, mandatory testing and certification for telecom equipment (referred to as MTCTE) went into effect for modems, private automatic branch exchange systems, and other products, the first tranche in a sweeping system of required in-country tests for telecom equipment. The tests run up to $78,000 per product at government labs (no price caps have been set for commercial labs) and will eventually cover all ICT products, so the cost of the duplicative testing will eventually total in the hundreds of millions per year, according to industry estimates. Moreover, the Indian government has approached several Indian IT companies to help establish testing labs in India to implement the new requirements. American companies could, therefore, be

[31] Aditya Kalra and Aditi Shah, RBI Sticking With Plan to Force Payments Firms to Store Data Locally: Sources, Reuters (Oct. 10, 2018), https://in.reuters.com/article/india-data-localisation/rbi-sticking-with-plan-to- force-payments-firms-to-store-data-locally-sources-idINKCN1MK2G9.

[32] Government of India, National Telecom M2M Roadmap (New Delhi: Government of India, Ministry of Communication and Information Technology, Department of Telecommunications, 2015).

[33] Panel Report, India – Certain Measures Relating to Solar Cells and Solar Modules, WT/DS456/R (Feb. 24, 2016). See WTO website, https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds456_e.htm.

compelled to hand over sensitive design information to a lab controlled by Indian competitors or else risk being barred from selling in the Indian telecom market.

For medical devices, of particular concern are Draft Quality Control Orders (QCOs) issued by the Department of Pharmaceuticals on February 15, 2019, that would require mandatory certification by the Bureau of Indian Standards (BIS) for surgical blades, surgical gloves, and other medical devices. The Draft QCOs would require that costly testing take place in BIS-approved laboratories. Several of the standards referenced are outdated and in one case would require deviation from that international standard. Importantly, the Draft QCOs conflict with the process underway at the Central Drugs Standard Control Organization (CDSCO), India's health authority, to register medical devices not currently regulated through a digital portal. We ask that rather than implementing the costly and duplicative Draft QCOs, India prioritize the CDSCO process by bringing an increasing number of medical devices under CDSCO regulation.

VI. Mandatory Beverage Alcohol Standards and Labeling Requirements

On April 1, 2019, new mandatory beverage alcohol standards and labeling requirements went into effect (The Food Safety Standards (Alcoholic Beverages) Regulations, 2018). AFTI is concerned that the final standard did not address concerns related to the general definition of whiskey, the requirement to provide an ingredient list, maximum alcohol content levels, the use of analytical parameters, and other required statements. In a particularly troubling development, the final draft did not provide explicit protection for Bourbon and Tennessee Whiskey as distinctive products of the United States.

VII. Access to Dairy Markets

India is one of the largest dairy markets in the world. Since 2003, India has maintained unscientific requirements for dairy imports and refused extensive good-faith efforts to restore trade in dairy products between the United States and India. Currently, the United States lacks a dairy certificate required by the Government of India to accompany all exports. The United States has proposed making use of an existing Indian labeling regulation and proposing to adopt an approach that would similarly label U.S. products as "vegetarian" or "non-vegetarian." India should accept this proposal and thereby restore access. It is important to note that solving the dairy certificate issue would not establish fully open dairy trade with India, but would increase annual U.S. dairy exports by up to $100 million, depending on the scope of the resolution. India still maintains sizable dairy tariffs that allows it to control access to its market. Rather, fixing this issue would simply ensure that U.S. producers have an equal opportunity to supply any needed imports into this large and growing market.

VIII. Conclusion

AFTI appreciates the opportunity to comment for the 2020 NTE Report on Foreign Trade Barriers and for the work of USTR and its counterparts throughout the government to address these important concerns. AFTI would be happy to answer any questions that the Committee may have.